



IFW

## PATENT APPLICATION

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q92149

Tomoyuki HASEGAWA, et al.

Appln. No.: 10/561,214

Group Art Unit: 1614

Confirmation No.: 2252

Examiner: Not yet assigned

Filed: December 19, 2005

For: METHANESULFONIC ACID SALT OF PYRAZOLOPYRIMIDINE COMPOUND,  
CRYSTAL THEREOF, AND PROCESS FOR PRODUCING THE SAME

### SUBMISSION OF ENGLISH TRANSLATION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Attached please find a copy of an English Translation of the International Preliminary Examination Report received from the Applicants, to advance prosecution in the event such is not readily available from the International Bureau. Claims 1-19 and 21-23 of the application were found to be novel, involve an inventive step and include industrial applicability.

Respectfully submitted,

Mark Boland  
Registration No. 32,197

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON DC SUGHRUE/265550

65565

CUSTOMER NUMBER

Date: December 29, 2006

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rules 44bis.3(c) and 72.2)

To:

OHIE, Kunihisa  
OHIE Patent Office  
Selva-Ningyocho 6F  
14-6, Nihonbashi-Ningyocho 2-chome  
Chuo-ku, Tokyo 103-0013  
JAPON

'06. 5. 11

Date of mailing (day/month/year) 04 May 2006 (04.05.2006)	
Applicant's or agent's file reference ONF-5058PCT	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/JP2004/009263	International filing date (day/month/year) 24 June 2004 (24.06.2004)
Applicant ONO PHARMACEUTICAL CO., LTD. et al	

## 1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

## 2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

## 3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 70 10

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference ONF-5058PCT	FOR FURTHER ACTION		See item 4 below
International application No. PCT/JP2004/009263	International filing date ( <i>day/month/year</i> ) 24 June 2004 (24.06.2004)	Priority date ( <i>day/month/year</i> ) 25 June 2003 (25.06.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ONO PHARMACEUTICAL CO., LTD.			

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).		
2.	This REPORT consists of a total of 6 sheets, including this cover sheet.		
	In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.		
3.	This report contains indications relating to the following items:		
	<input checked="" type="checkbox"/> Box No. I	Basis of the report	
	<input checked="" type="checkbox"/> Box No. II	Priority	
	<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	
	<input type="checkbox"/> Box No. IV	Lack of unity of invention	
	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	
	<input type="checkbox"/> Box No. VI	Certain documents cited	
	<input type="checkbox"/> Box No. VII	Certain defects in the international application	
	<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application	
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).		

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No. +41 22 740 14 35	Date of issuance of this report 24 April 2006 (24.04.2006)
	Authorized officer  Masashi Honda  Telephone No. +41 22 338 70 10

# PATENT COOPERATION TREATY

TRANSLATION

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**ONF-5058PCT**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/009263**

International filing date (day/month/year)

**24.06.2004**

Priority date (day/month/year)

**25.06.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**ONO PHARMACEUTICAL CO., LTD.**

1. This opinion contains indications relating to the following items:

- |                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input checked="" type="checkbox"/> | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application  |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/009263

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language  
\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/009263

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 20

because:

☒ the said international application, or the said claims Nos. 20  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The invention described in claim 20 includes a method of treatment of the human body by therapy and contains items for which an International Preliminary Examination is not required.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 20

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form ☐ has not been furnished

☐ does not comply with the standard

the computer readable form ☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/009263

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-19, 21-23 YES

Claims \_\_\_\_\_ NO

Inventive step (IS)

Claims 1-19, 21-23 YES

Claims \_\_\_\_\_ NO

Industrial applicability (IA)

Claims 1-19, 21-23 YES

Claims \_\_\_\_\_ NO

2. Citations and explanations:

Document 1 : WO 02/053565 A1

Document 2 : WO 97/11946 A1

Document 3 : JP 5-112571 A

The inventions described in claims 1-19 and 21-23 are neither described in any of the documents cited in the ISR nor obvious to a person skilled in the art.

In addition to describing "8-(3-Pentylamino)-2-methyl-3-(2-chloro-4-methoxy-phenyl)-6,7-dihydro-5H-cyclopenta[d]pyrazolo[1,5-a]pyrimidine hydrochloride," document 1 also describes its CRF antagonism activity, but no document cited in the ISR describes or suggests advantages in pharmaceutical production wherein the stability of a compound is improved by a specified salt or crystallization of a specified salt.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/009263

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claim 16 describes a drug wherein a compound of claim 1 is combined with another drug, but results of pharmacological testing shown in the description are only CRF antagonism activity of the compound of claim 1, and combinations with other drugs cannot be stated to be adequately supported by the description.